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LEVEL 1™

OPERATOR'S MANUAL

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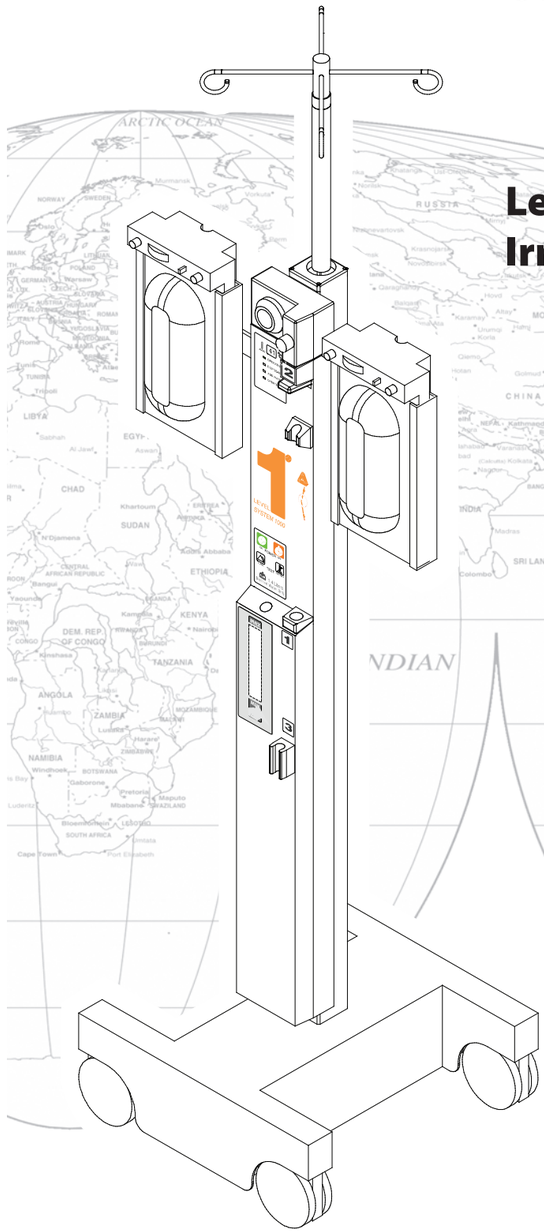

Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer

REF H-1129 115V

Rx ONLY

smiths medical

LEVEL 1™

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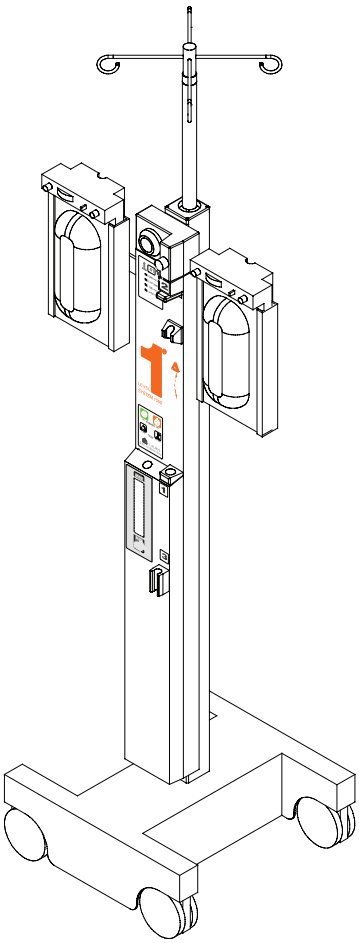
REF H-1129 115V



OPERATOR'S MANUAL

P/N 4533800-EN Rev. 004

smiths medical

Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer Operator's Manual
Part Number: 4533800-EN Rev. 004 (2007-08)

This revision supercedes all previous revisions.

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The products described are covered by one or more of the following U.S. Patent Nos. 4,759,749; 4,878,537; 4,900,308; 5,063,994; 5,097,898; 5,417,274 and 5,512,043.

For further information, please call your local Smiths Medical representative or Smiths Medical direct at 1-800-258-5361 or +1-781-878-8011.

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SECTION 1

About this Manual

This Operator's Manual describes the set-up, use, and maintenance of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer.

These instructions contain important information for safe use of the product. Read the entire operator's manual, including Warnings and Cautions, before using the product. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.

The manual is intended for use by individuals trained in the healthcare and biomedical professions.

WARNING

- Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including all warnings and cautions could result in death or serious injury to the patient or user.

Conventions Used in this Manual

Convention	Description
Note	A Note statement alerts the user to important information that requires attention.
CAUTION	A Caution statement alerts the user to conditions that may cause physical injury and/or an adverse effect on the device or its performance.
WARNING	A Warning statement alerts the user to conditions that may cause serious personal injury or death to the user or patient.

SECTION 2

Description

The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer has been designed for safe, rapid, in-line warming of irrigating fluids as they are administered to patients. This non-invasive method employs single-use, disposable, irrigating sets that include a Heat Exchanger and may include a Gas Vent.

Gas Vent

Some Level 1® NORMOFLO® Irrigation Warming Sets (Disposable Sets) include a Gas Vent. The Gas Vent releases micro-bubbles of gas from fluids as they are warmed.

Temperature Control

The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer employs a safe recirculating solution heating system, inherently free of any "hot spots." The primary temperature control circuit sets the recirculating solution to a temperature of approximately 41.7°C for efficient heat exchange and maximum fluid warming.

Automatically Operating Pole

The Level 1® H-1129 NORMOFLO® Irrigation Fluid Warmer includes an electronically operated pole that lifts fluid bags with the touch of a switch.

Level 1® NORMOFLO® Irrigation Warming Sets

Disposable Sets available for use on the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer are listed below.

- IR-40
- IR-500
- IR-600
- IR-700

SECTION 3

Indications for Use

The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer (Fluid Warmer) is designed for use by trained medical personnel for in-line warming of irrigating fluids.

SECTION 4

Important Safety Information

This section covers information for prescribers and guidelines for safe use of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer (Fluid Warmer).

WARNINGS

Death or serious injury may occur to the patient or user if these warnings are not followed:

- Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including all warnings and cautions, could result in death or serious injury to the patient or user.
- Do not use the Fluid Warmer in high-energy fields such as: MRI, X-RAY, portable and mobile RF communications equipment, and other such devices. The Fluid Warmer may act as a projectile in a strong magnetic field, cause image artifacts, or not function as intended.
- Do not bend the heat exchanger. Bending may damage the heat exchanger allowing communication between the recirculating solution and irrigation fluid path, resulting in the delivery of inappropriate fluids.
- Exposed conductor on MAINS power cord can cause an electrocution hazard. Remove device from service if MAINS power cord has exposed wires.
- Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required. Failure to clear the over temperature condition or to take the device out of service may result in death or serious injury to the patient.

Continued

Continued from previous page

WARNINGS

- The Fluid Warmer is for use only with Smiths Medical supplied or approved parts, accessories, and Irrigation Disposable Sets. The device may not function as intended with the use of unapproved parts, accessories, or Disposable Sets.
- Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.
- If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately.
- Do not operate the Fluid Warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.The risk of explosion exists if the Fluid Warmer is operated in a potentially explosive environment.
- No user-serviceable parts. All service must be performed by Smiths Medical or an authorized representative.
- Disposable Sets are supplied with a sterile fluid path which may be compromised if the caps are not in place. Do not use Disposable Set if spike caps and end caps are not securely in place, or if connections are not secure as the fluid path may not be sterile and may cause death or serious injury to the patient.
- Disposable Sets are for single use only. To reduce the risk of cross contamination, do not reuse Disposable Sets.
- Do not overextend Automatic Pole; if Automatic Pole is overextended the Fluid Warmer may become unstable.
- For high pressure irrigating use only. Pressure chamber not for I.V. use.
- Do not exceed pressure specified for the Disposable Set in use.

CAUTIONS

Physical injury to the patient, user, and/or an adverse effect on the device or its performance may occur if these cautions are not followed:

- Do not use the Fluid Warmer if equipment or Disposable Set malfunction is evident.
- Avoid contact with surgical lights or other overhead fixtures. Maximum Transport Load: 12 liters at maximum height of 2.25 meters (7 ft 4 inch), 6 liters at maximum height of 2.54 meters (8 ft 4 inch) from floor to bag hanger.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- The 3L Pressure Cuff accessory should not be pressurized above 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of some Disposable Sets or the cuff itself.
- When loading fluid bags into Pressure Chambers, choose a hanging hook that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If bag ports are positioned above this slot, diminished flow could occur.

SECTION 5

Out of the Box-Assembly

This device must be assembled and tested by authorized Smiths Medical personnel, an authorized distributor of Smiths Medical, or a qualified person authorized by the institution prior to placing the device into service.

The following steps describe how to assemble and do preliminary setup of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer (Fluid Warmer).

Step 1 Verify Components of the Fluid Warmer

Step 2 Assemble Fluid Warmer to Base

Step 3 Install the Pressure Chambers

Step 4 Attach the Fluid Bag Hanger

Step 5 To Set Up the 3-Liter (3L) Pressure Accessory

Step 6 Disinfect the Recirculating Solution Reservoir

Step 7 Preparation for Use

Step 8 Perform Electrical Safety Tests

Read through the instructions completely prior to setting up the device.

Note: After unpacking the system, recycle packaging material according to hospital policy for recyclable materials.

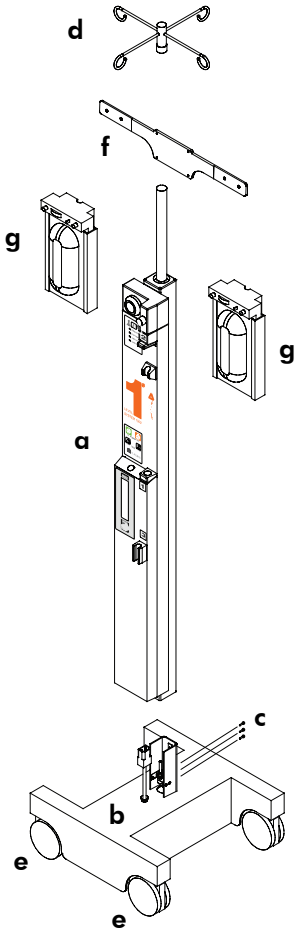
Step 1 - Verify Components of the Fluid Warmer

Check the contents of all packaging to verify that the following components are present. If any parts are missing or damaged, do not use the Fluid Warmer. Do not substitute parts not supplied by Smiths Medical. Contact Smiths Medical for replacement parts.

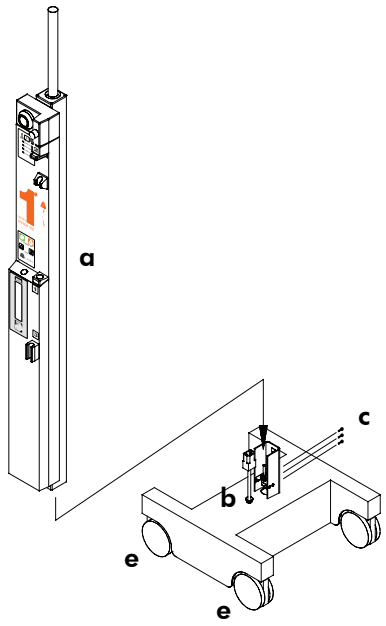
The H-1129 Series Fluid Warmer packaging contains the following items:

Components Checklist

Qty	Component
1	Fluid Warmer and Automatic Pole Assembly (**a**)
1	Base Assembly (**b**)
3	Pole to Base Assembly screws (**c**) 10-32x1/2 inch long button head
1	Fluid Bag Hanger (**d**)
4	Casters - 2 locking (**e**) and 2 non-locking
1	HI-2 Bracket (**f**)
2	HI-2 Pressure Chambers (**g**)
1	Operator's Manual (not shown)
1	O-Ring Kit (not shown)
1	Assembly Wrench - 1/8 inch Allen (not shown)
1	Assembly Wrench - 5/64 inch Allen (not shown)
1	Piece 61 cm (24") black tubing (not shown)
2	J-clips (not shown)
1	3L Pressure Accessory package: 1 box of 5 disposable 3L Pressure Cuffs, 2 3L Adapter Assemblies (not shown)
4	HI-2 Thumb Screws (not shown)
4	Bracket Screws (not shown)
2	Straight Fittings [In-Line Pneumatic Fitting (not shown)]



Step 2 - Assemble Fluid Warmer to Base

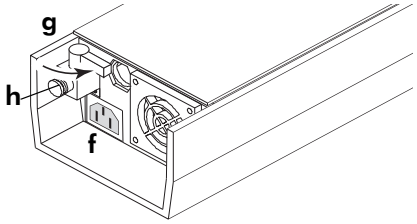


1. Insert two locking casters (**e**) into the base as shown, and then insert the two non-locking casters. Bring the base upright; then remove the 3 screws (**c**) from the Base Assembly.
2. With the power cord on the Base Assembly facing forward, gently slide the Fluid Warmer/Pole Assembly (**a**) onto the Base Assembly (**b**).

   Note: Do not drop the Fluid Warmer/Pole Assembly onto the Base Assembly.

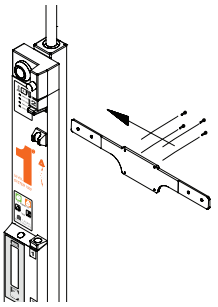
3. Re-install the three screws (**c**) and tighten using the 1/8 inch Allen wrench supplied.

   Note: Take care not to strip the screw threads.



4. Plug the power cord from the Base Assembly into the Auxiliary Outlet (**f**) on the bottom of the Fluid Warmer/Pole Assembly (**a**).
5. Turn valve, located on the bottom of the device, perpendicular to stem (**g**) of the Fluid Warmer as shown.
6. Remove 61 cm (24”) black tubing from its package. Push one end of the tubing into the opening of valve stem (**h**) until it can go no further; gently pull the tubing to make sure it is secure.
7. Remove one J-clip from its package and peel off the backing to expose the adhesive. Adhere the J-clip to the back of the Fluid Warmer, approximately 13 cm (5”) above the valve stem.
8. Push the tubing into the J-clip.

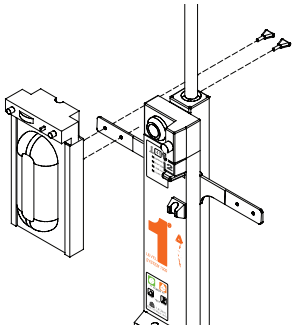
Step 3 - Install the Pressure Chambers



1 Remove the four HI-2 Bracket screws located just under the Pressure Gauge Box on the back of the Fluid Warmer and slide the HI-2 Bracket through the slot between the Fluid Warmer and the Power Pole.

   Re-install the four screws through the bracket and tighten with the 5/64" wrench supplied.

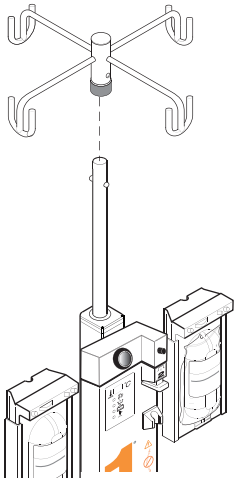
   Note: Make sure the two slanted ends of the HI-2 Bracket face towards the front of the Fluid Warmer.



2 Feed the thumb screws through the back of the HI-2 Bracket and into the HI-2 Pressure Chamber; hand tighten.

3 Connect the two ends of the 1/4" black pneumatic tubing from the Pressure Gauge Box and the Pressure Chamber to the In-Line Pneumatic Fittings by pressing them firmly into the Pneumatic Fittings until they can go no further.

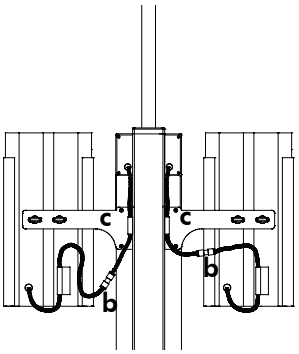
Step 4 - Attach the Fluid Bag Hanger

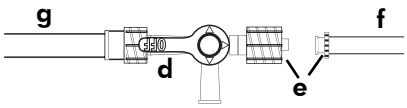


1 Slide the Fluid Bag Hanger on top of the pole.

2 Align with tabs.

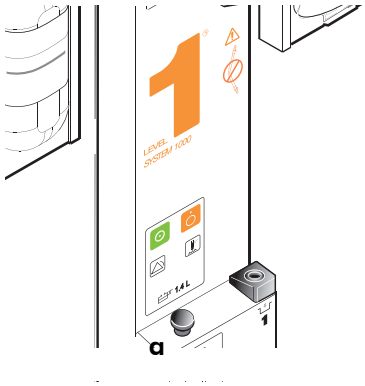
3 Press down and snap into place.





Step 5 - To Set Up the 3-Liter (3L) Pressure Accessory

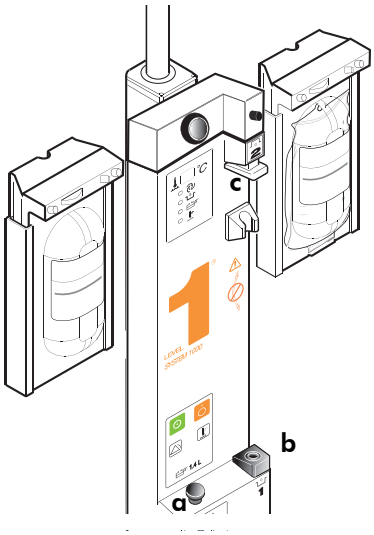
1. Disconnect the black pneumatic tubing from each In-Line Pneumatic Fitting (**b**). Press on the red ring closer to the 1L pressure chamber, and gently pull on the black tubing.
2. Remove the black pneumatic tubing from the J-clips (**c**) on the sides of the pole.
3. Make sure the Adapter Assembly's valve handle is in the OFF/ VENT position (**d**).
4. Insert the black tube from the Adapter Assembly into the In-Line Pneumatic Fitting (**b**).
5. Connect the Adapter Assembly (**g**) to the 3L Pressure Cuff (**f**) by connecting the male and female Luer connectors (**e**) securely.
6. Slide the 3L Fluid Bag into the Pressure Cuff, and hang them from the Fluid Bag Hanger.
7. Repeat steps 3-6 if you are using a second 3L Pressure Cuff.



Step 6 - Disinfect the Recirculating Solution Reservoir

1. Remove the fill-port plug (**a**) on the reservoir.
2. Prepare a 0.3% hydrogen peroxide/sterile water solution for the reservoir. Mix 140 ml of 3% hydrogen peroxide solution and 1,260 ml of sterile water.
3. Fill the reservoir with 1.4 liters of 0.3% hydrogen peroxide/ sterile water solution.
4. Replace the fill-port plug.
5. Insert a Disposable Set into the Fluid Warmer.
6. Insert the power cord into a properly grounded receptacle.
7. Turn the Fluid Warmer ON. Let the solution circulate for a 30-minute disinfection period.
8. Turn the Fluid Warmer OFF.
9. Empty the reservoir.
10. Remove the Disposable Set and discard according to established hospital procedures.

Step 7 - Preparation for Use



1. Remove the fill-port plug (**a**) on the front of the warming unit and fill the reservoir to the maximum level with 1.4 liters of one of the following solutions:
   - 0.3% Hydrogen Peroxide/Sterile Water Solution: Mix 140 ml of 3% hydrogen peroxide and 1,260 ml of sterile water.
     Note: If this option is selected, always use a 0.3% hydrogen peroxide/sterile water solution when adding solution to the reservoir.
   - Distilled Water

   Note: Change the recirculating solution every 30 days.
2. Replace the fill-port plug.
3. Lubricate O-Rings in #1 Block (**b**) and #2 Block (**c**). Place a small amount of silicone lubricant, provided in the supplied O-Ring Kit, on a cotton swab and apply all around the inside of each O-Ring.

Step 8 - Perform Electrical Safety Tests

Perform all applicable electrical safety tests as required per institutional procedure. These include but are not limited to:

- Leakage current
- Hypot
- Ground bond test

WARNING

- Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle, resulting in death or serious injury to the patient or user.

The Electrical Safety Check must be performed by qualified personnel authorized by the institution to perform such testing. The Safety Check must be performed and documented at least once per year, or according to institutional policy.

SECTION 6

Principle of Operation

The schematic illustration on the following page depicts the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer operations. The primary operations are described below.

Fluid Warming

The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer utilizes a solution reservoir housed in a controller unit. Recirculating solution is warmed and pumped through a heat exchanger (a part of the Disposable Set). The solution is returned to the reservoir for continuous recirculation and remains isolated from the patient and from the irrigating fluid path. The recirculating solution is heated to a pre-set temperature. The system continuously monitors and controls the recirculating solution temperature. The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer is designed to stop fluid warming and provide audible and visual alarms in the event of an over-temperature condition.

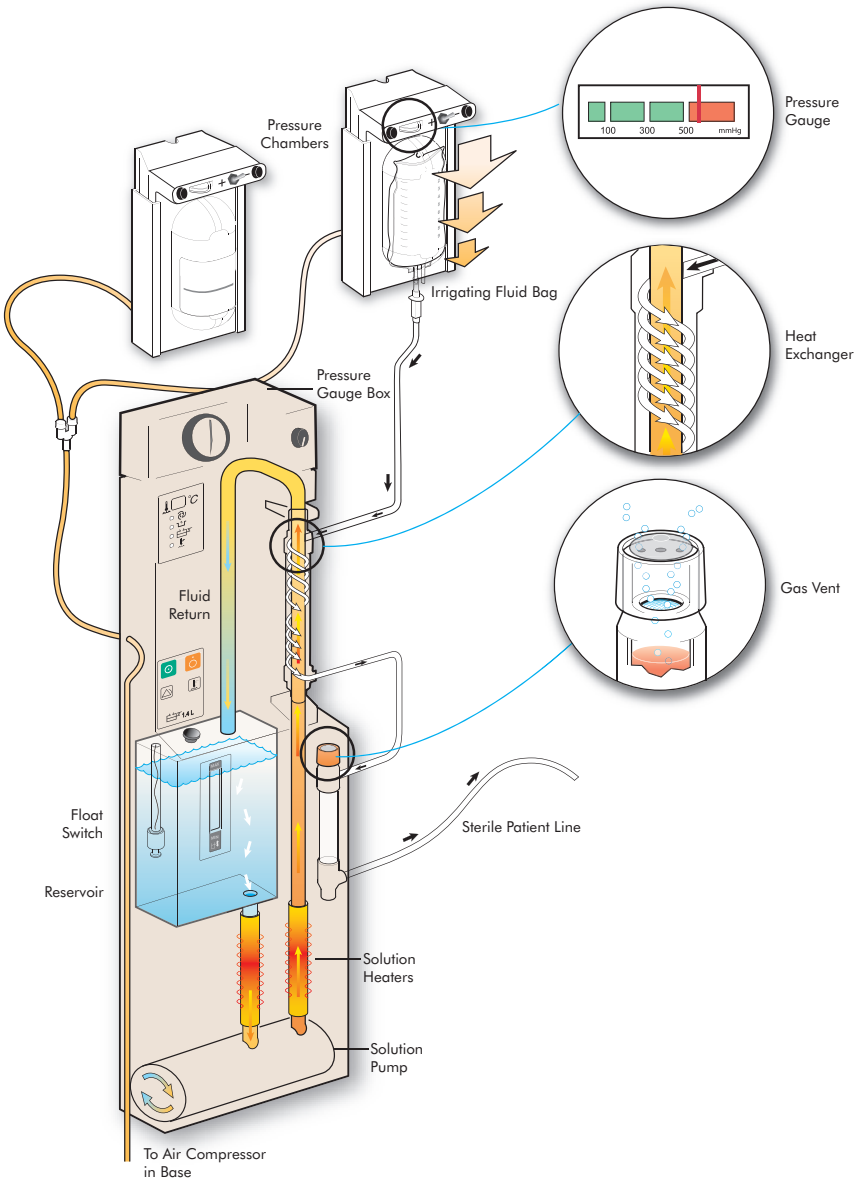
Pressurized Fluid Delivery

The Fluid Warmer provides pressurized fluid delivery through the use of an on-board compressor and two Pressure Chambers. The Pressure Chambers pressurize the fluid bags for fast fluid delivery. A control panel on each Pressure Chamber displays the pressure in the chamber. A pressure regulator knob lets you select the desired pressure; a dial gauge displays the selected pressure.

H-1129

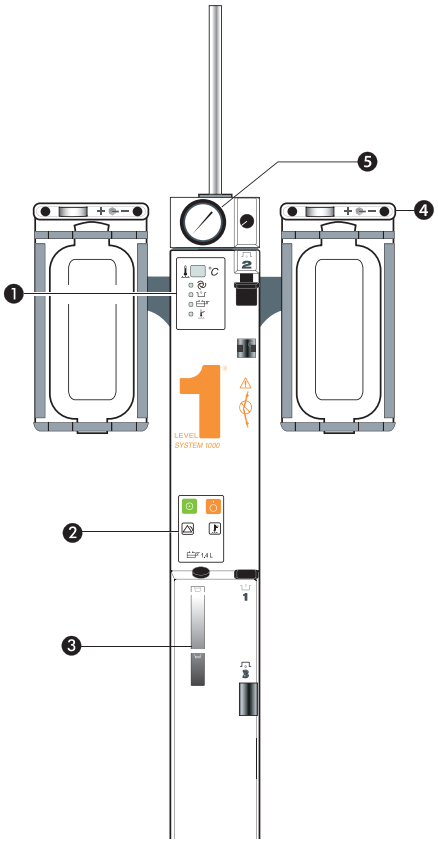
NORMOFLOW® Irrigating Fluid Warmer

Principle of Operation Schematic



SECTION 7

Controls and Displays



Five locations on the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer govern how the device is controlled and where function indicators are displayed. They are called out in the figure on the facing page and defined in the list below.

1 Fluid Warmer Display Panel

2 Power and Alarm Test Panel

3 Reservoir Level Display

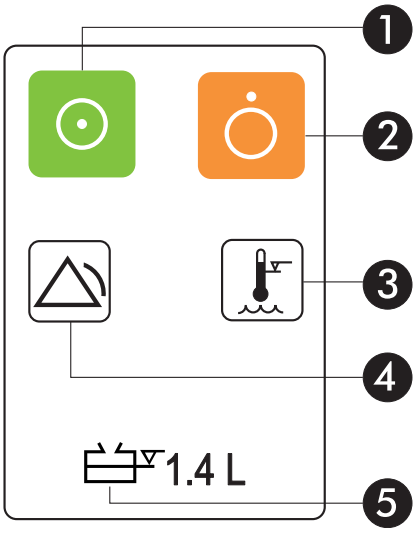
4 Pressure Chamber Control Panel

5 Pressure Gauge Box

The Fluid Warmer has three Interlocks, which are defined in this section. The Interlocks detect for correct installation of a Disposable Set.

Fluid Warmer Power and Alarm Test Panel

The Power and Alarm Test Panel is located on the front of the Fluid Warmer directly above the reservoir fill-cap. This panel contains four pressure-sensitive buttons that are activated when pressed. Refer to the Power Alarm Test Panel figure, whose numbered call-outs correspond to descriptions of the buttons and the functions they perform.



Button/Function

1 Power ON Button
The green button on the top left of the Power and Alarm Test Panel powers on the device. The green Automatic Operation LED on the Fluid Warmer Display Panel illuminates when the Power ON button is activated, and a Disposable Set is in place.

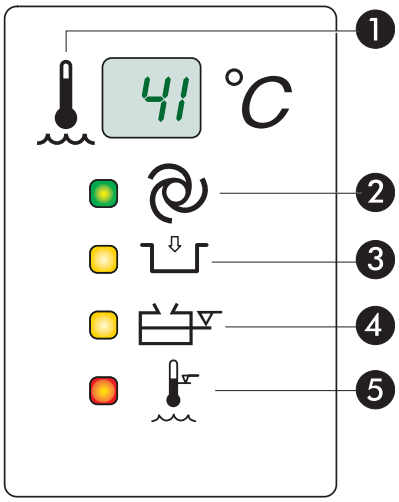
2 Power OFF Button
The Power OFF is the orange button to the right of the Power ON button on the Power and Alarm Test Panel. This button turns off power to the unit. The green Automatic Operation LED on the Display Panel will turn off when this button is pressed.

3 Over Temperature Test Button
The Over Temperature Test is used to confirm the proper operation of the Over Temperature circuitry. Testing the circuitry requires that the Fluid Warmer is at operating temperature (41°C). Once this is established, press and hold the button until the alarm activates. Then, release the button. The Over Temperature alarm continues to function. Clear the alarm mode by turning the device off, then back on.

4 Fluid Warmer Alarm Signal Test Button
The Fluid Warmer Alarm Signal Test is used to confirm proper operation of the visual and audible alarm indicators. Press and hold this button to test circuitry. Then, release the button. The Over Temperature alarm continues to function. Clear the alarm mode by turning the device off, then back on.

5 Reservoir Capacity
Capacity for recirculating solution reservoir is 1.4 liters.
Use recirculating solution. Do not exceed maximum capacity.

Fluid Warmer Display Panel



The Fluid Warmer Display Panel provides continuous information about the operation of the Fluid Warmer. A liquid crystal display (LCD) indicates recirculating solution temperature. Just below the LCD, four light-emitting diodes (LEDs) indicate operation modes for the device. For identification purposes, the diodes are shown illuminated.

1 Recirculating Solution Temperature
The temperature of the recirculating solution is displayed in the LCD panel. The temperature is displayed in degrees Celsius.

Note: This is NOT the temperature of fluid delivered to the patient—the display reflects the temperature of the recirculating solution.

2 Automatic Operation LED
This green LED indicator illuminates when the power is ON and the Disposable Set has been properly installed. When lit, this indicates the Fluid Warmer is operating.

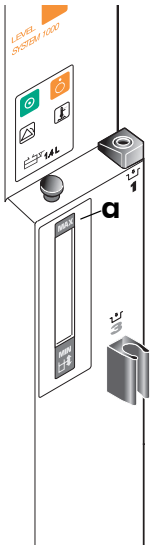
3 Check Disposables LED
This yellow LED indicator illuminates and an audible attention signal activates when the Disposable Set is not properly installed. See “Interlocks” on page 19 for directions on clearing the Check Disposables alarm.

4 Add Recirculating Solution LED
This yellow LED indicator illuminates and an audible attention signal activates when reservoir is low. Additional recirculating solution must be added to the reservoir. Maximum capacity for the reservoir is 1.4 liters.

5 Over Temperature LED
This red LED indicator illuminates and an audible warning signal activates when the recirculating solution is over the acceptable temperature for safe use.

Reservoir Level Display

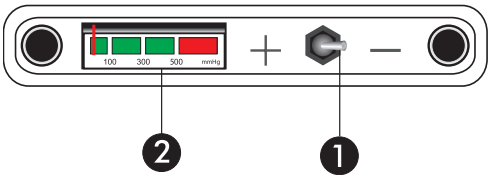
The Reservoir Level Display has a clear window for viewing the amount of recirculating solution present in the reservoir. Check the reservoir to ensure the solution level is near the maximum level indicator (**a**). If the recirculating solution level is too low, the Add Recirculating Solution LED on the Display Panel illuminates and an audible attention signal activates.



Pressure Chamber Control Panel

1 Pressurize / Unpressurize Toggle Switch

This switch is used to pressurize the Pressure Chamber.



a To Pressurize the Pressure Chamber

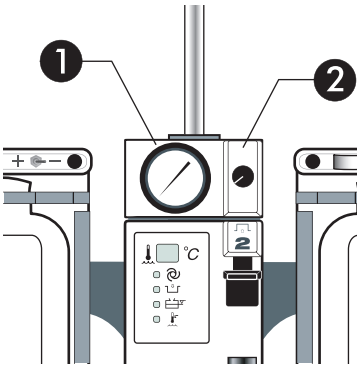
With Pressure Chamber door closed and latched, push Toggle Switch all the way to the plus (+) pressurized position. This applies pressure in the Pressure Chamber when the Fluid Warmer is turned ON.

b To Unpressurize the Pressure Chamber

To release pressure from the Pressure Chamber, push Toggle Switch all the way to the minus (–) unpressurized position. Pressure is released on the fluid bag in the Pressure Chamber.

2 Pressure Gauge

When the Toggle Switch is in the plus (+) pressurized position and the Fluid Warmer is ON, this gauge displays the operating pressure in the Pressure Chamber.



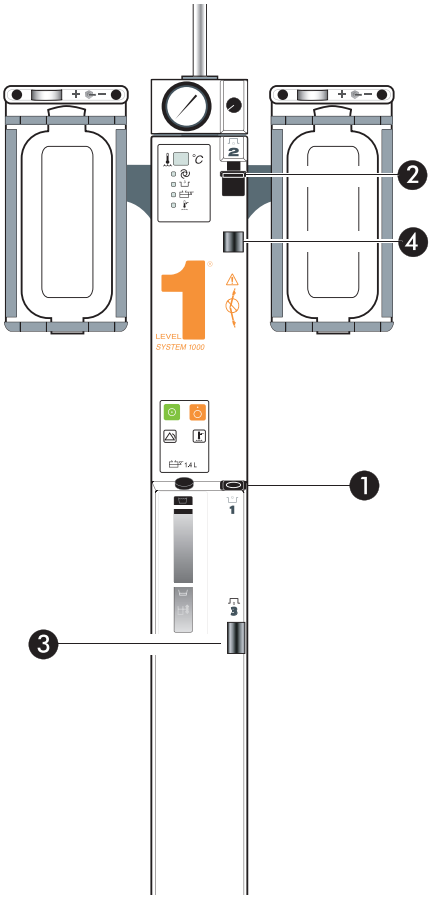
Pressure Gauge Box

1 Pressure Dial Gauge

When pressure is activated, the Pressure Dial Gauge displays the selected pressure as you adjust the Pressure Regulator Knob (**b**).

2 Pressure Regulator Knob

When pressure is activated, the Pressure Regulator Knob adjusts the level of pressurization. As you turn the knob, the Pressure Dial Gauge displays the selected pressure.



Interlocks

The Fluid Warmer has three Interlocks that detect for proper installation of a Disposable Set's components.

Refer to the figure to identify the positions of Interlocks.

Note: Block **1** is not an Interlock. It cannot detect if a Disposable Set is not correctly installed. It is identified here because it is an essential step for proper installation of the Disposable Set components.

The three Interlocks are located on the Fluid Warmer and check for proper installation of:

- **2** Heat Exchanger (top end)
- **3** Gas Vent
- **4** Heat Exchanger (guide)

Interlocks **2**, **3**, and **4** prevent the Fluid Warmer's pump from circulating reservoir solution if the Disposable Set's Heat Exchanger and Gas Vent are not installed properly.

If Check Disposables Alarm is Activated on the Fluid Warmer

a Check Heat Exchanger for proper installation in Block **1**, and Interlocks **2** and **4**.

b Press Heat Exchanger down firmly in Block **1** to secure in O-Ring.

c Press Interlock **2** tab down firmly to engage the Interlock switch.

d Check Gas Vent installation in Interlock **3**.

SECTION 8

Operation

The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer (Fluid Warmer) functions are monitored and controlled by four interfaces/control panels located on the Fluid Warmer. The four interfaces are:

- Fluid Warmer Power and Alarm Test Panel
- Fluid Warmer Display Panel
- Pressure Chamber Control Panel
- Pressure Gauge Box

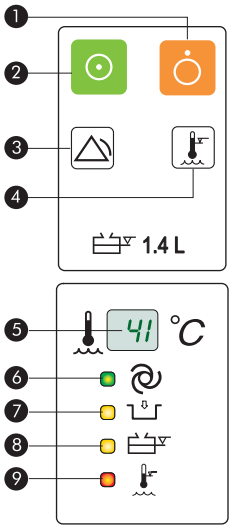
In the table on the following page, operation of the device is represented in terms of the two interfaces that control specific device functions. The numbers call out individual Modes of Operation activated or indicated on the interface.

Operational modes

- OFF Mode
- ON/Automatic Operation for Fluid Warmer
- Alarm Test Mode
- Over Temperature Test Mode
- Check Disposables Mode
- Add Recirculating Solution Mode
- Over Temperature Alarm Mode
- Pressurized Mode
- Unpressurized Mode

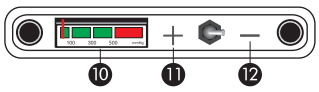
The modes of operation are individually defined in the following section. This includes a description of each mode, activation and/or monitoring of the mode, mode characteristics, and clearing of the mode state.

Operation Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer

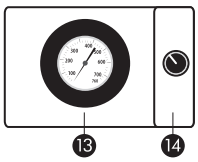


Fluid Warming

Function	Interface	#	Description	Indicator/ Alarm Signal	
				Visible	Audible Beep
Fluid Warming	Fluid Warmer Power and Alarm Test Panel	1	OFF	None	None
		2	ON	LEDs display	None
		3	Alarm Test	LEDs display	1/second
		4	Over Temperature Alarm Test	LEDs display	1/second
	Fluid Warmer Display Panel	5	Temperature Display	LCD Readout	None
		6	Automatic Operation	Green LED	None
		7	Check Disposables	Yellow LED	1/5 seconds
		8	Add Recirculating Solution	Yellow LED	1/5 seconds
		9	Over Temperature	Red LED	1/second



Pressurized Fluid Delivery	Pressure Chamber Control Panel	10	Pressure Gauge	Numbered Dial	None
		11	Pressurized	+ Symbol	None
		12	Unpressurized	– Symbol	None



Pressure Regulation	Pressure Gauge Box	13	Pressure Dial Gauge	0-500 mmHg	None
		14	Pressure Regulator Knob	None	None

Modes of Operation

WARNING

- If any visual indicator does not illuminate or the audible signal does not sound, do not use the Fluid Warmer. Remove the device from service immediately. Death or serious injury may occur to the patient or user if this warning is not followed.

OFF Mode

Power is off only for a part of the equipment. The MAINS are still connected. Press the OFF button (**a**) on the Power and Control Panel to turn the device off.

a

ON/Automatic Operation Mode for Fluid Warmer

The Fluid Warmer enters Automatic Operating mode when a Disposable Set is properly installed and the device is turned ON. This is done by pressing the ON button (**b**).

b

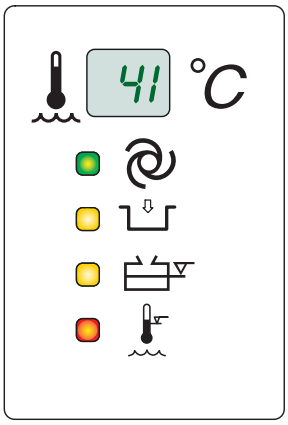
Mode characteristics

- The green Automatic Operating LED on the Display Panel illuminates (**c**).
- Fluid warming begins.
- Pressure is provided by activating the Pressure Chambers.

c

d

e



Alarm Test Mode

The Alarm Test mode is used to test the visual and audible indicators of the Fluid Warmer. To enter Alarm Test Mode, press and hold the Alarm Test button (**d**) on the Fluid Warmer's Control Panel.

Mode characteristics

- All visual indicators on the Fluid Warmer's Display Panel (**e**) illuminate.
- The Fluid Warmer's audible alarm activates.
- When the Alarm Test button is released, the Over Temperature LED and audible alarm remain active.

To clear this mode:

- Turn the Fluid Warmer OFF and then back ON.

Over Temperature Test Mode

The Over Temperature Test mode is used to test the operation of the Fluid Warmer's Over Temperature Circuitry. To enter this mode, press and hold the Over Temperature Test button (**f**) on the Fluid Warmer Control Panel with the Fluid Warmer at operating temperature (41°C).

f

Mode characteristics

- The red Over Temperature LED (**g**) illuminates.
- An audible warning signal activates.

g

To clear this mode

- Turn the Fluid Warmer OFF and then back ON.

Temperature Display

The Temperature Display functions when the Fluid Warmer is powered ON. Temperature is displayed in degrees Celsius.

Check Disposables Mode

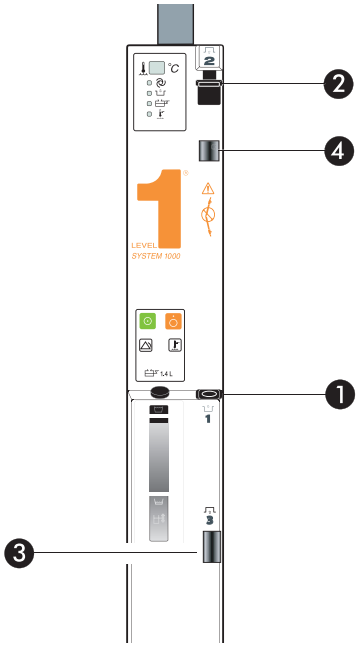
The Check Disposables mode of the Fluid Warmer indicates a missing or improperly installed Disposable Set.

Mode characteristics

- The Check Disposables yellow LED (**a**) on the Fluid Warmer's Display Panel illuminates.
- An audible attention signal beeps.
- Reservoir solution circulation is stopped; fluid warming stops.
- Pressure Chambers continue to operate.

To clear this mode

Install a Disposable Set or check the Disposable Set installation as follows:



- Check Heat Exchanger for proper installation in Block **1**, and in Interlocks **2** and **4**.
- Press Heat Exchanger down firmly in Block **1** to secure in O-Ring.
- Press Interlock **2** tab down firmly to engage the Interlock switch.
- Check Gas Vent installation in Interlock **3**.

Add Recirculating Solution Mode

The Add Recirculating Solution mode of the Fluid Warmer indicates that the solution level in the recirculating solution reservoir is below its minimum level.

Mode characteristics

- The yellow Add Recirculating Solution LED (**b**), on the Fluid Warmer's Display Panel, illuminates.
- An audible warning signal beeps.
- Solution circulation stops; fluid warming stops.
- Pressure Chambers continue to operate.
- Fluid flow to the patient continues.

To clear this mode

- Add recirculating solution to the Fluid Warmer's reservoir.

Over Temperature Alarm Mode

The Over Temperature Alarm mode is entered when the temperature of the recirculating solution reservoir is at or above 43.9°C (± 0.1°C).

WARNING

- Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required. Failure to clear the over temperature condition or to take the device out of service may result in death or serious injury to the patient.

c

Mode characteristics

- The Over Temperature LED warning light illuminates (**c**).
- An audible warning signal beeps.
- Solution circulation is stopped; fluid warming stops.
- Pressure Chambers continue to operate.
- Fluid flow to the patient continues.

To Clear Over Temperature Alarm mode

Do the following:

- Turn the Fluid Warmer OFF and then back ON.

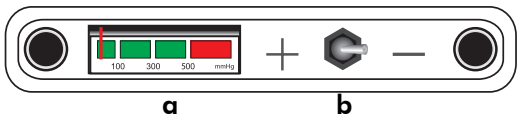
Pressurized Mode

- The HI-2 Pressure Chambers deliver fluids at an increased flow rate with the application of pressure upon the fluid bags. Flow rate varies according to temperature, Disposable Set used, and the amount of clamping applied to the roller clamps.

Pressurization is enabled when:

- A fluid bag is installed in the Pressure Chamber.
- The Fluid Warmer is turned ON.
- The Pressure Chamber Toggle Switch (1) is in the plus (+) pressurized position.

Mode Characteristics



- The Fluid Warmer must be ON for the Pressure Chamber to work.
- Pressure is applied to the fluid bag in the Pressure Chamber according to the amount specified by the Pressure Regulator Knob (**d**).
- Pressure is indicated on the Pressure Gauge (**a**).

To exit this mode

- Push the Pressure Chamber Toggle Switch (**b**) to the minus (-) position.

Unpressurized Mode

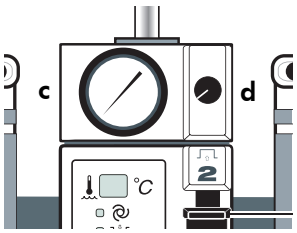
- Disable pressurization by turning the Pressure Chamber Toggle Switch (**b**) on the Pressure Chamber to the minus (-) unpressurized position.

Mode Characteristics

- Pressure is released from the Pressure Chamber.
- A fluid bag can be removed or loaded into the Pressure Chamber.

Pressure Regulation Mode

Pressure Regulator Knob



- The Pressure Regulator Knob (**d**) functions when the device is ON and the Pressure Chamber Toggle Switch (**b**) is in the plus (+) position. The knob lets you adjust the pressure in the Pressure Chamber.
- The Pressure Regulator Knob controls both Pressure Chambers if both are activated.

Pressure Dial Gauge

- When the Toggle Switch is in the plus (+) pressurized position and the Fluid Warmer is ON, this gauge (**c**) displays the selected pressure as you adjust the Pressure Regulator Knob.
- The Pressure Dial Gauge controls both Pressure Chambers if both are activated.

SECTION 9

Operating Instructions

The Operating Instructions are grouped into three segments. Read through each section BEFORE performing a procedure.

WARNINGS

- The Fluid Warmer is for use only with Smiths Medical supplied or approved parts, accessories, and Irrigation Disposable Sets. The device may not function as intended with the use of unapproved parts, accessories, or Disposable Sets, resulting in death or serious injury to the patient.
- Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle, resulting in death or serious injury to the patient or user.
- Do not bend the heat exchanger. Bending may damage the heat exchanger allowing communication between the recirculating solution and irrigation fluid path, resulting in the delivery of inappropriate fluids, which could result in death or serious injury to the patient.
- Do not use the Fluid Warmer in high-energy fields such as: MRI, X-RAY, portable and mobile RF communications equipment, and other such devices. The Fluid Warmer may act as a projectile in a strong magnetic field, cause image artifacts, or not function as intended.
- Exposed conductor on MAINS power cord can cause an electrocution hazard. Remove device from service if MAINS power cord has exposed wires.
- Do not operate the Fluid Warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.The risk of explosion exists if the Fluid Warmer is operated in a potentially explosive environment.

CAUTIONS

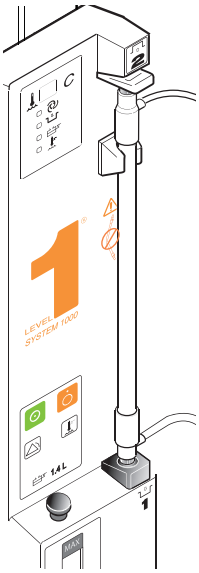
Physical injury to the patient, user, and/or an adverse effect on the device or its performance may occur if these cautions are not followed:

- Do not use the Fluid Warmer if equipment or Disposable Set malfunction is evident.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- When loading fluid bags into Pressure Chambers, choose a hanging hook that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If bag ports are positioned above this slot, diminished flow could occur.

9.1 Set Up for Use

WARNINGS

- Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including all warnings and cautions, could result in death or serious injury to the patient or user.
- Disposable Sets are supplied with a sterile fluid path which may be compromised if the caps are not in place. Do not use Disposable Sets if spike caps and end caps are not securely in place, or if connections are not secure as the fluid path may not be sterile and may cause death or serious injury to the patient.
- Disposable Sets are for single use only. To reduce the risk of cross contamination, do not reuse Disposable Sets.

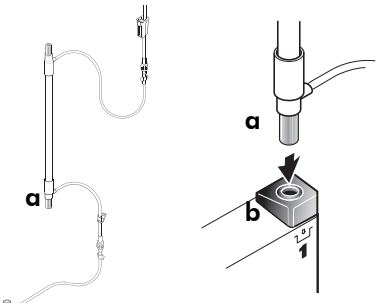


A–Install the Irrigation Warming Set

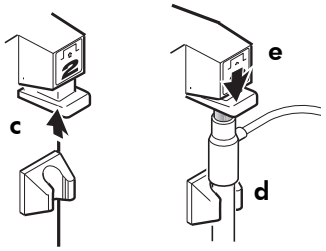
The installation sequence for the Disposable Set corresponds to the numbered Blocks marked 1-2-3 on the Fluid Warmer.

Remove the Disposable Set from its packaging and review the Instructions for Use provided. Do not remove spike caps at this time.

1 Push the bottom end of the Heat Exchanger (**a**) [the end near the Gas Vent] into #1 Block (**b**). Press the Heat Exchanger down firmly to properly seat in the block.



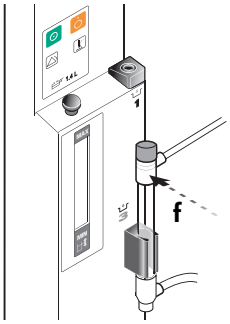
2 Slide #2 Block up (**c**). Snap Heat Exchanger into guide (**d**). Press firmly into place to ensure it is properly seated. Slide #2 Block down (**e**), push down firmly to secure.



3 Align the Gas Vent (**f**) to the #3 Block, and press it into place.

4 Press the green Power ON button, located on the Power and Alarm Test Panel, to turn ON the Fluid Warmer.

- If the Disposable Set is correctly installed, the green Operation light illuminates on the display panel.
- If the Disposable Set is incorrectly installed, the Fluid Warmer's Check Disposables attention indicator illuminates and the audible attention signal activates. Check the installation of the Disposable Set following the directions provided in "Interlocks" on page 19.



B–Priming Irrigating Disposable Sets

WARNING

- Do not overextend Automatic Pole; if Automatic Pole is overextended the Fluid Warmer may become unstable.

Note: Different Disposable Sets have different configurations. Refer to the applicable Irrigating Disposable Set Instructions for Use for details. The following steps use the IR-500 Disposable Set.

1 Aseptically deliver the Patient Line (**g**) into the sterile field.

2 Close clamps (**a**), (**b**) and (**c**).

3 Make sure Pressure Chamber Toggle Switch is at the minus (-) unpressurized position.

4 Open the Pressure Chamber doors and hang fluid bags on bag hangers.

5 Using aseptic technique, remove Spike Caps, and spike irrigation fluid containers. Be sure tubing is not twisted or kinked.

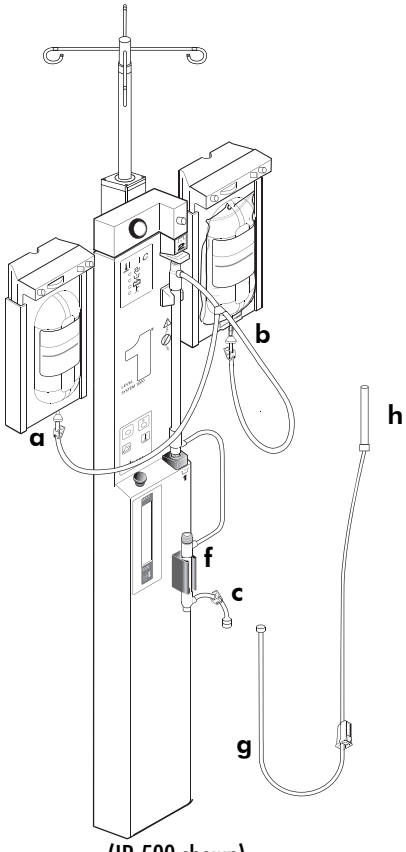
6 Close and latch Pressure Chamber doors.

7 Turn ON the Pressure Chambers by pushing both Toggle Switches to the plus (+) pressurized position.

8 Open clamps (**a**) and (**b**), and allow Gas Vent (**f**) to completely fill with fluid.

Note: See "C–Attach Disposable Hand Piece or Specialized Irrigation Disposables" on page 31 to connect hand pieces or irrigation disposables that use a standard bag spike connector.

9 Receive capped end of Patient Line (**g**) from sterile field.



(IR-500 shown)

10 Remove orange caps from the Gas Vent (**f**) and from the Patient Line (**g**).

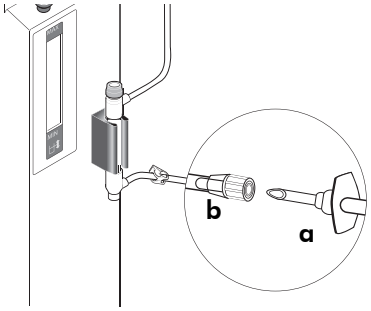
11 Attach Patient Line (**g**) to the Gas Vent (**f**).

12 In the sterile field, use Scope Connector (**h**) to attach Patient Line (**g**) to the scope.

13 Open clamp (**c**) with Patient Line (**g**) running uphill from Gas Vent (**f**) to the scope.

14 Close either clamp (**a**) or (**b**).

C–Attach Disposable Hand Piece or Specialized Irrigation Disposables



The following procedure describes how to use the NORMOFLO® Irrigation Fluid Warming Set with disposable hand pieces or specialized irrigation disposables that use a standard bag spike on the fluid supply tubing.

1 Complete steps 2-8 in "B–Priming Irrigating Disposable Sets" on page 30.

2 Remove orange cap from the Gas Vent and the Spike Cap from the hand piece or specialized irrigation disposable.

3 Firmly insert the Bag Spike (**a**) into the connector on the Gas Vent (**b**).

4 Complete setup and priming of the hand piece or specialized irrigation disposable as per the instructions for use.

D–Test the Audible and Visual Alarms

Test the visual and audible alarm signals by performing the following steps.

1 Press and hold the Alarm Test button on the Fluid Warmer's Power and Alarm Test Panel.

- All Fluid Warmer visual alarm LEDs illuminate and the audible alarm signals beep.

2 Release the Alarm Test button; the Over Temperature alarm continues.

3 Clear the Over Temperature alarm condition.

- Turn the Fluid Warmer OFF and then back ON.

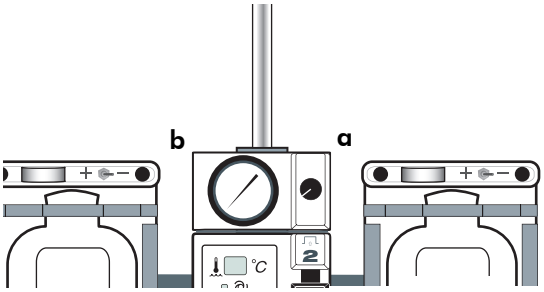
9.2 Use of the Fluid Warmer

Use of the Fluid Warmer requires that the steps in "9.1 Set Up for Use" on page 28 have been completed.

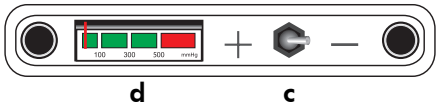
A–Pressurize the 1-Liter (1L) Pressure Chambers

WARNING

- For high pressure irrigating use only. Pressure chamber not for I.V. use.
- Do not exceed pressure specified for the Disposable Set in use.



1. Adjust the Pressure Regulator Knob (**a**) on the Pressure Gauge Box to set desired level on Dial Gauge (**b**). The maximum pressure is approximately 500 mmHg.
2. Push Pressure Chamber Toggle Switch (**c**) to the plus (+) pressurized position. Observe Pressure Gauge (**d**) to make sure that required pressure is achieved.

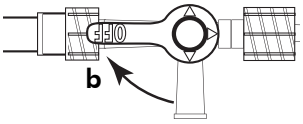


Note: A pressure relief valve automatically activates if pressure goes above 550 mmHg.

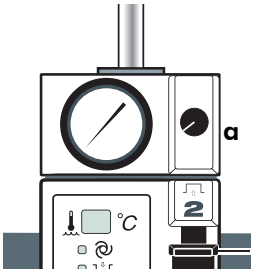
B–Prepare the 3-Liter (3L) Pressure Cuff Accessory for Use

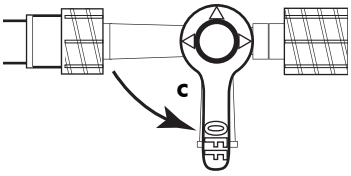
CAUTION

The 3L Pressure Cuff accessory should not be pressurized above 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of some Disposable Sets or the cuff itself.



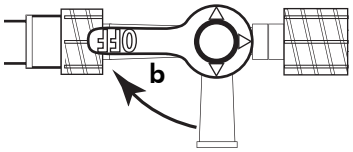
1. Make sure the H-1129 Fluid Warmer is set up for operation.
2. Slide the 3L fluid bag into the 3L Pressure Cuff, and hang them from the fluid bag hanger on the automatic pole.
3. Make sure the Adapter Assembly's valve handle is in the OFF/VENT position (**b**).
4. Spike the 3L fluid bag.
5. Turn ON the Fluid Warmer, and adjust the Pressure Regulator Knob (**a**) (on the Pressure Gauge Box) to the desired pressure (not to exceed 300 mmHg).





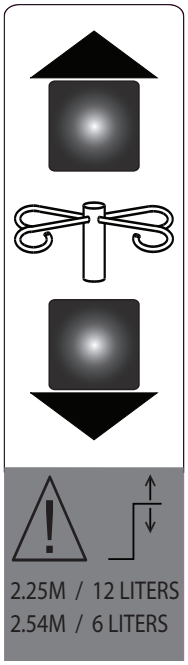
6 Turn the valve handle on the Adapter Assembly to the ON position (**c**). The Pressure Cuff begins to inflate. The Pressure Gauge drops to zero temporarily, and then steadily increases to the desired pressure.

The unit is ready for use.



7 To deflate the Pressure Cuff, turn the valve handle (**c**) back to the OFF/VENT position (**b**).

C– Adjust the Automatic Pole



WARNING

- Do not overextend Automatic Pole; if Automatic Pole is overextended the Fluid Warmer may become unstable.

CAUTION

- Avoid contact with surgical lights or other overhead fixtures. Maximum Transport Load: 12 liters at maximum height of 2.25 meters (7 ft 4 inch), 6 liters at maximum height of 2.54 meters (8 ft 4 inch) from floor to bag hanger.

- To raise the pole, push and hold the Membrane Switch Up Arrow located on the left side of the Automatic Pole until the pole reaches the desired height, or until the pole reaches its highest position; release the Membrane Switch.

  Note: Observe that the Disposable Set is not snagged as the Pole is extended.

- To lower the pole, push and hold the Membrane Switch Down Arrow until the pole reaches the desired height, or until the pole reaches it lowest position; release the Membrane Switch.

D–Change the Fluid Bag

1. Close the clamp under empty bag.
2. Push the Pressure Chamber Toggle Switch to the minus (-) unpressurized position to release pressure in the pressure chambers.
3. Open the pressure chamber door and remove the fluid bag from the fluid bag hanger.
4. Remove the spike from the empty fluid bag.
5. Hang a new fluid bag.
6. Spike the fluid bag. Be sure tubing is not twisted or kinked.
7. Close and latch Pressure Chamber doors.
8. Push the Pressure Chamber Toggle Switch to the plus (+) pressurized position

9.3 After Use

1. Close all clamps.
2. Push the Pressure Chamber Toggle Switch to the minus (-) unpressurized position to release pressure in the pressure chambers.
3. Turn the Fluid Warmer OFF.
4. Open the Pressure Chamber door and remove the fluid bag.
5. Properly discard the Disposable Set in containers marked for biohazardous materials. Dispose by incineration, or follow hospital policies and procedures applicable for the disposal of biohazardous material.
6. Visually check the condition of the device. Remove from service any unit that shows physical damage.
7. Clean the device with warm soapy water.

SECTION 10

Troubleshooting

Only qualified personnel authorized by the institution should perform any routine maintenance and repairs to the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer.

The following two tables feature general troubleshooting information along with slow flow rate troubleshooting.

General Troubleshooting Guide

Problem	Check the following
No Power	Check to see if unit is plugged in and power is turned ON. Be sure the unit is plugged into a working MAINS receptacle.
Disposables Alarm activates	Check to see that the Heat Exchanger and Disposable Set are properly installed.
Add Recirculating Solution Alarm activates	Fill reservoir to the maximum reservoir level with recirculating solution.
Over Temperature Alarm activates	Press OFF button to clear alarm. Then, press ON button to power on. If the Fluid Warmer continues to alarm, discontinue use of the medical device and remove from service. Contact Smiths Medical or an authorized representative for service.
Hot Cabinet	Check the air inlet on the bottom of the unit. Remove any blockage or dust to insure adequate air flow.
Heat Exchanger hard to install	Lubricate O-Rings in #1 and #2 block heat exchanger sockets with silicone lubricant. Silicone lubricant part # 80-04-002.
Loud Compressor	Verify pneumatic tubing is fully seated into fittings.
Green Automatic Operating LED doesn't light up during setup	Verify unit is plugged into MAINS. If still no LED illumination, discontinue use of the medical device and remove from service.

Problem	Check the following
Pressure Chambers not activated or Pressure Cuff does not inflate	• Pressure Chamber Toggle Switch(es) should be in the plus (+) pressurized position. • Pressure Chamber door must be closed with the latch secured. • Check to see if the Pressure Regulator Knob is properly adjusted. • Check the 1/4" black pneumatic tubing; make sure it is properly connected and fully seated. • Check to see if the Fluid Warmer is properly installed onto the Base Assembly. • Check to see if the unit is plugged into a working MAINS receptacle, and power is turned ON. • Make sure the valve handle on Adapter Assembly is in the plus (+) pressurized position, not the minus (-) vent position.

Slow Flow Rate Troubleshooting

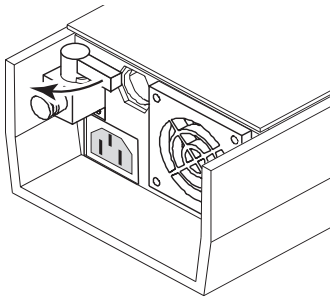
Problem	Check the following
Fluid bag not fully spiked or bag port twisted	Make sure the membrane of the fluid bag port is fully pierced by the bag spike and that the neck of the bag port is not twisted.
Clamps partly engaged	Verify all clamps are fully open.
Clamps left in the clamped position for long periods	Leaving clamps fully clamped for long periods will cause the tubing to become deformed. Do not leave clamps closed for extended periods of time.
Kinked tubing	Verify that no tubing kinks are present.

SECTION 11

Testing

This unit should be tested by hospital biomedical personnel prior to placing it in service. All testing and maintenance should be performed by qualified personnel authorized by the institution to perform such testing. If qualified personnel are not available, contact Smiths Medical. If the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer and installed accessories do not pass the tests, discontinue use of the medical device and remove from service. Contact Smiths Medical or an authorized representative for service. Testing requires a Level 1® NORMOFLO® Irrigation Warming Set (Disposable Set) to be installed in the Fluid Warmer.

Add Recirculating Solution Alarm



The Fluid Warmer is equipped with a float switch that senses the level of the recirculating solution in the reservoir. When the solution level is too low, an LED on the Display Panel illuminates and an audible alarm beeps. In the Add Recirculating Solution Alarm mode, the circulating pump is not running. With a Disposable Set in place and the unit turned on, test the Add Recirculating Solution Alarm by draining the solution until the level has dropped below the minimum reservoir level. The Add Recirculating Solution Alarm should activate. To drain recirculating solution from the Fluid Warmer, turn the drain valve on the bottom of the unit 90 degrees clockwise and allow some of the recirculating solution to drain into a container.

Check Disposables Alarm

Three Interlocks detect the proper installation of a Disposable Set in the Fluid Warmer. If a Disposable Set is not properly installed and the power is ON, an indicator will illuminate and an audible alarm beeps. With the Fluid Warmer ON, the Interlocks should be tested one at a time by performing the following steps.

1. Heat Exchanger (top end) Interlock - Slide the #2 Block up slowly. The Check Disposables indicator illuminates and the audible alarm beeps.
2. Heat Exchanger (guide) Interlock - Gently pull on the middle of the heat exchanger. The Check Disposables indicator illuminates and the audible alarm beeps.

3 Gas Vent Interlock - Pull the top of the Gas Vent Assembly from the #3 Block. The Check Disposables indicator illuminates and the audible alarm beeps.

Over Temperature Test

a

Do the following:

1 Insure that the Fluid Warmer is at operating temperature (41°C).

2 Press and hold the Over Temperature Test button (**a**).

3 The Over Temperature LEDs illuminate, and an audible alarm beeps.

4 Release the Over Temperature Test button.

5 Over Temperature LED and audible alarm signal remains active.

Clear the Alarm mode

- Turn the Fluid Warmer OFF and then back ON.

Fluid Warmer Alarm Signal Test

b

The Alarm Test button is used to confirm proper operation of the visual and audible alarm indicators.

Do the following

1 Press and hold the Alarm Test button (**b**).

2 The Check Disposables, Add Recirculating Solution, and Over Temperature LEDs illuminate and an audible alarm beeps.

3 Release the Alarm Test button.

4 Over Temperature LED remains lit, and the audible alarm continues to beep.

Clear the Alarm mode

- Turn the Fluid Warmer OFF and then back ON.

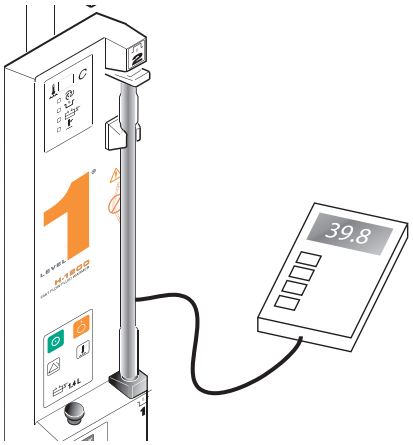
Performance Testing

Cold Start Test

Store the Fluid Warmer unit in a room where the room temperature is approximately 21°C (70°F).

1. Put a Disposable Set in place.
2. Record the start time.
3. Turn the Power button ON.
   - The green system operational indicator illuminates.
   - Rapidly rising numbers will appear on the recirculating solution temperature display.
   - Within 60 seconds (±) the display should read at least 30°C.
   - In 3 to 10 minutes the display should read 41°C. The Temperature Set Point is 41.7°C (+/- 0.3°C).

Note: If the Fluid Warmer does not pass the Cold Start Test, it should be removed from use and returned to Smiths Medical or an authorized representative for service.



Calibration Test

One approved way to confirm proper calibration of the recirculating solution temperature is to use the Level 1® Thermal Calibration Well (TCW) (Part Number 80-03-002). A replacement filter (F-10 or F-30) must be in place to utilize the TCW.

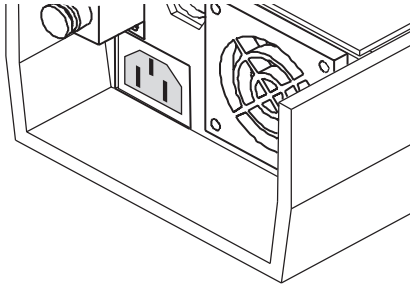
Note: Use of the TCW requires a digital thermometer NIST traceable and accurate within 0.1°C. Required probe size: 0.099" OD (Outside Diameter) maximum (0.25 cm) 0.50" - 1.50" long (1.27-3.81cm).

Alternative Calibration Test

Another approved way to confirm proper calibration of the recirculating solution temperature is to use the Level 1® DSTA-40 TEMP CHECK (Part Number 80-01-004).

Calibration Test with DSTA-40

The DSTA-40 TEMP CHECK (DSTA-40) is an electronic thermometer used to verify the recirculating solution operating temperature of the Fluid Warmer. The DSTA-40 uses thermistor technology to sense the temperature of the recirculating solution temperature for the Fluid Warmer. The recirculating solution temperature is displayed by a liquid crystal display (LCD). The DSTA-40 is powered from the auxiliary outlet of the Fluid Warmer. No batteries are required.



Note: The Level 1® DSTA-40 TEMP CHECK is available for purchase from Smiths Medical.

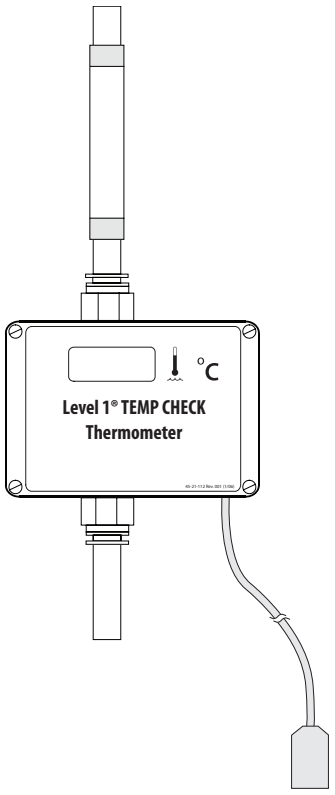
Proper calibration of recirculating solution temperature

Confirm proper calibration of recirculating solution temperature by performing the following steps:

1. Unplug the power cord for the base assembly from the auxiliary outlet on the bottom of the Fluid Warmer.
2. Plug the DSTA-40 TEMP CHECK into the auxiliary outlet.
3. Install the DSTA-40 TEMP CHECK in the heat exchanger position (#1 Block and #2 Block).
4. Install a test filter in the #3 Block.
5. Turn the Fluid Warmer ON. Allow to warm up until the DSTA-40 temperature display stabilizes.
6. Compare the DSTA-40 TEMP CHECK temperature display with the temperature display on the Fluid Warmer's Display Panel.

   Using a flat-head screwdriver, open the Fluid Warmer's faceplate at the left and right corners, and look at the LCD temperature display. If the DSTA-40 reads 41.7C and the Fluid Warmer's temperature display is within the range of 41.4 C - 42.0 C, the calibration is OK. Push the Fluid Warmer's faceplate back into place.

   Note: The Fluid Warmer's temperature display must read within 0.3°C of the Level 1® DSTA-40 TEMP CHECK display on a properly calibrated unit.



7. Unplug the DSTA-40 TEMP CHECK and plug the power cord from the base assembly into the auxiliary outlet.

Periodic Electrical Testing

Earth Leakage

The Fluid Warmer must be tested in accordance with EN 60601-1. The earth leakage current test should be performed with the immersion heater circuit in the full ON condition; for this reason the leakage current test should be performed on units which have room temperature recirculating solution in the reservoir. Units not meeting this standard should be returned to Smiths Medical or an authorized representative for service.

Ground Continuity

The Fluid Warmer must be tested in accordance with EN 60601-1.

WARNING

- Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle, resulting in death or serious injury to the patient or user.

SECTION 12

Maintenance

Only qualified personnel authorized by the institution should perform any routine maintenance and repairs to the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer (Fluid Warmer). Maintenance is scheduled with each use, every 30 days, and annually. The tasks are detailed below.

Maintenance Performed with Every Use

Clean and inspect the Fluid Warmer after each use.

Clean the Exterior

- Clean the entire Fluid Warmer after every use. Use only mild detergents, water, and a soft cloth.
- To disinfect external surfaces, use a 10% bleach/sterile water solution.

General Inspection

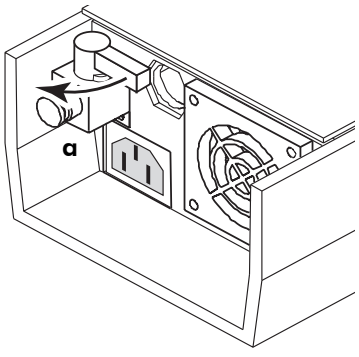
- Check the condition of the Fluid Warmer with a visual inspection. Remove from service any unit that shows physical damage.
- If the Disposable Set does not install easily, lubricate the O-Rings as directed in the following section.

Maintenance Performed Every 30 Days

Lubricate O-Ring Seals

It is not necessary to disassemble the blocks to lubricate the O-Rings.

1. Place a small amount of silicone grease on a cotton swab.
2. Apply the silicone grease along the O-Rings in the bottom #1 Block, and top #2 Block Heat Exchanger sockets.



Change Recirculating Solution

1. Place a container under the drain valve of the Fluid Warmer.
2. Drain the recirculating solution by turning the drain valve (**a**) clockwise 90 degrees.
3. When all solution has drained from the reservoir, close the drain valve.
4. Refill the reservoir with distilled water or 0.3% hydrogen peroxide/sterile water solution (mix 140 ml of 3% hydrogen

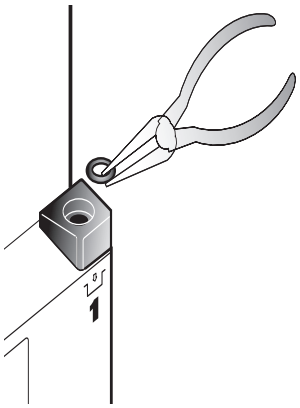
peroxide solution and 1,260 ml of sterile water). The reservoir holds 1.4 liters.

Maintenance Performed Every 12 Months

Disinfect the Reservoir

1. Place a container under the drain valve of the Fluid Warmer.
2. Drain the recirculating solution by turning the drain valve clockwise 90 degrees.
3. When all solution has drained from the reservoir, close the drain valve.
4. Remove the fill-port plug on the reservoir.
5. Prepare a 0.3% hydrogen peroxide/sterile water solution. Mix 140 ml of 3% hydrogen peroxide solution and 1,260 ml of sterile water.
6. Fill the reservoir with 1.4 liters of 0.3% hydrogen peroxide/sterile water solution.
7. Replace the fill-port plug.
8. Insert a Disposable Set into the Fluid Warmer.
9. Turn the Fluid Warmer ON. Let the solution circulate for a 30-minute disinfection period.
10. Turn the Fluid Warmer OFF.
11. Empty the reservoir; close the drain valve.
12. Remove the Disposable Set and discard according to established hospital procedures.
13. Refill the reservoir to its 1.4-liter capacity.
    - If using distilled water, refill the reservoir with distilled water.
    - If using a peroxide solution, refill the reservoir with a 0.3% hydrogen peroxide/sterile water solution.

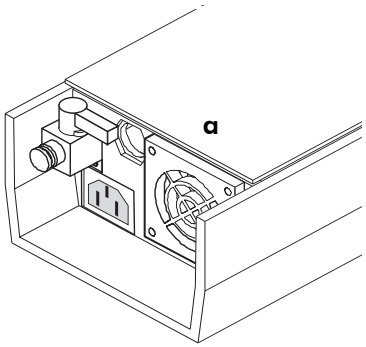
Change O-Rings



Change the O-Rings in the #1 Block and #2 Block.

1. Remove each O-Ring from its socket by pulling it out with a pair of needle-nose pliers or by prying it out with a small screwdriver.
2. Lubricate the new O-Rings from the O-Ring Kit.
3. Press each O-Ring into its socket.

Clean Fan Filter



The Fan Filter **(a)** is located on the bottom of the Fluid Warmer. The fan guard snaps in place.

1. Unsnap and remove the fan guard from the bottom of the unit.
2. Remove the filter and clean it with warm soapy water.
3. When the filter is fairly dry, replace the fan guard and filter.

Testing Fluid Warmer Operation

Perform all the tests described in the testing section of this manual. See "Testing" on page 37.

- Add Recirculating Solution Alarm
- Check Disposables Alarm
- Over Temperature Alarm
- Performance Testing

Maintenance and Calibration Log

All maintenance and testing should be done by qualified personnel authorized by the institution to perform such maintenance. Regularly scheduled maintenance ensures proper functioning of the equipment. Refer to the table below for required tasks and frequency of routine maintenance.

Scheduled Maintenance and Calibration Checklist

Task	Every Use	Every 30 Days	Every 12 Months
Clean the Exterior	□		
General Inspection	□		
Change Recirculating Solution		□	
Lubricate O-Rings		□	
Disinfect Recirculating Solution Reservoir			□
Replace O-Rings			□
Clean Fan Filter			□
Perform Over Temperature Alarm Test			□
Test Add Recirculating Solution Alarm			□
Test Disposable Alarm			□
Perform Fluid Warmer Alarm Signal Test			□
Verify Temperature Calibration			□
Electrical Safety Tests			□

SECTION 13

Limited Warranty

Smiths Medical ASD, Inc. (the "Manufacturer") warrants to the Original Purchaser that the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer, not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, and excludes any accessory items or equipment used with the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer (not including accessories) which is defective if a claim is made during such one-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. **Parties Covered by this Warranty:** This warranty extends only to the Original Purchaser of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer. This warranty does not extend to subsequent purchasers. The Original Purchaser may be medical personnel, a hospital, or institution which purchases Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. **Warranty Performance Procedure:** Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Customer Service Department, Smiths Medical ASD, Inc., 160 Weymouth Street, Rockland, MA 02370, (800) 258-5361. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE LEVEL 1® NORMOFLO® H-1129 IRRIGATION FLUID WARMER. If authorized, the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. **Conditions of Warranty:** The warranty is void if the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer has been 1) repaired by someone other than the Manufacturer or its authorized agent; 2) altered so that its stability or reliability is affected; 3) misused; or 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Operator's Manual or use with non-approved accessories. Removal or damage to the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer serial numbers will invalidate this warranty.

D. **Limitations and Exclusions:** Repair or replacement of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.

2. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE LEVEL 1® NORMOFLO® H-1129 IRRIGATION FLUID WARMER FOR ANY PARTICULAR PURPOSE.

3. The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer for any particular medical treatment.

4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer for any particular medical treatment or for any medical complications resulting from the use of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

SECTION 14

Service

WARNING

- No user-serviceable parts. All service must be performed by Smiths Medical or an authorized representative.

All service must be performed by Smiths Medical, or an authorized service representative. Service by any other person or organization voids the warranty and transfers liability for malfunctions of the device to the servicing organization.

Warranty Service

Units received for repair which have not been obviously abused or impact damaged and are still under warranty will be promptly repaired and returned at no charge. See the limited warranty section of this manual. A no-charge purchase order is requested for tracking.

Non-Warranty Work

Units received which have suffered obvious abuse or impact damage and units no longer under warranty will be promptly inspected and a verbal estimate of repair cost will be supplied. A purchase order will be required from the hospital consistent with the verbal estimate. A written estimate will be provided upon request.

Before returning your Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer for service, contact Smiths Medical for Returned Goods Authorization. Be sure that ALL recirculating solution is drained from the unit before packing the Fluid Warmer for shipment.

Note: The Fluid Warmer must be cleaned and disinfected for repair shipment or it will be immediately returned as received.

Additional Documentation

Upon request Smiths Medical will provide the following documentation:

- Circuit diagrams
- Components parts list(s)
- Description of function
- Service and calibration instructions
- Disposal Information

Disposal Information

The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer contains lead that is used in solder of the electric assembly. When you are ready to dispose of the device, observe federal, state, and local codes or requirements for disposal of hazardous materials and for recycling of solid waste materials that may impact the environment.

Service Contacts

Contact your Smiths Medical, Technical Service Department or Smiths Medical, distributor at:

Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland, MA 02370 USA

USA/Canada 1-800-258-5361

www.smiths-medical.com

SECTION 15

Specifications

System Specifications

Standard Compliance	Guidelines	
Product Safety	EN 60601-1, UL 2601-1	
EMC	EN 60601-1-2, FCC 47 CFR Part 15, Class B	
Enclosure Protection	IEC 60529 IP Code: IPX1	
Fluid Warmers	ASTM F2172-02	
Physical	**Dimensions**	
Height, Overall	1.83 m	(6 ft)
Width, Overall	48.3 cm	(19 inches)
Depth, Overall	48.3 cm	(19 inches)
Weight Assembled, Dry	38.1 kg	(84 pounds)
Recirculating Solution Capacity	1.4 L	(0.37 gallons)
Air Source Pressure	0-500 mmHg	
Environmental	**Temperature**	**Humidity [%]**
Operation	10°C to 45°C	30 to 75
Transportation	0°C to 70°C	30 to 75
Storage	0°C to 70°C	30 to 75
Thermal	**Temperature**	
Temperature Set Point	41.7°C ± 0.3°C	
Over Temperature Set Point	43.9°C ± 0.1°C	
Electrical	**Type**	
Protection Against Electrical Shock	Class 1 Equipment, Type BF	
Mode of Operation	Continuous	
Type of Current	Alternating	
Ingress Protection Rating	IPX1	
MAINS Power Input	115VAC, 50/60 Hz, 12.0 Amps	
MAINS Auxiliary Power Supply Output	115VAC, 50/60 Hz, 1.5 Amps	

Electromagnetic Environmental Recommendations

Recommended separation distances between portable and mobile RF communications equipment and the Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer

The Level 1® NORMOFLO® H-1129 Irrigation Fluid Warmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Fluid Warmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fluid Warmer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d=[3.5/V1]√P	**80 MHz to 800 MHz** d=[3.5/E1]√P	**800 MHz to 2.5 GHz** d=[7/E1]√P
0.01	0.116	0.116	0.233
0.1	0.368	0.368	0.737
1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 1 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Level 1® NORMOFLO® Irrigation Warming Sets (Disposable Sets)

REF	**Product Description**
IR-40	Normothermic Irrigating Set
IR-500	Normothermic Irrigating Set
IR-600	Normothermic Irrigating Set
IR-700	Normothermic Irrigating Set with vented spikes for use with rigid plastic containers

Disposable Set Accessories

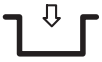
REF	**Product Description**
IR-6	2-spike adapter to convert IR/IRI series disposables to a 4-spike configuration
IR-7	2-spike adapter to convert IR/IRI series disposables to a 4-spike configuration - for use with rigid plastic containers

SECTION 16

Symbols

Symbols	Definitions
	Type BF Equipment
IPX1	Protected Against Dripping Water
	Catalog Number
	Serial Number
	Part Number
	Batch Code
	Manufacturer
	Date of Manufacture
	Quantity
	Protective Earth [Ground]
	Alternating Current
	Do Not Reuse
	Attention, see instructions for use
	Electric Shock Hazard
	Latex Free

Symbols	Definitions
STERILE EO	Sterilized using ethylene oxide
STERILE EO STERILE FLUID PATH	Sterile Fluid Path, Ethylene oxide gas sterilized
Rx ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
CLASS 1	Device is class type 1 equipment
	Protective earth terminal
	Consult instructions for use.
	Do not use if package is damaged.
	Temperature Limitation
	Humidity Limitation
	Use by
	Recyclable Product
	Do not bend heat exchanger
	Alarm Test
	ON —Only for a part of the equipment. MAINS are connected
	OFF —Only for a part of the equipment. The MAINS are still connected

Symbols	Definitions
	Automatic Operation
	Recirculating Solution Temperature
	Over Temperature Test (Recirculating Solution Over Temperature)
	Add Recirculating Solution
	Check Disposables, Check Tubing
	Maximum Reservoir Level
	Minimum Reservoir Level
	Device has been tested by National Technical Systems, a nationally recognized technical laboratory, to meet U.S. requirements for safety.
	Collect separately for electrical and electronic equipment.
+	Pressurized
−	Unpressurized

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